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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,018	07/07/2003	Ursula-Henrike Wienhues	2923-543	8627

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

NOTIFICATION DATE	DELIVERY MODE
02/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/613,018	WIENHUES ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/7/08; 6/30/08; and 12/9/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-22 and 25* is/are pending in the application.

4a) Of the above claim(s) *16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-15, 19-22, and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/776,188.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 7, 2008; June 30, 2008; and December 9, 2008 have been entered.

Status of the Claims

2. The amendment to the claims received on September 6, 2006 canceled claim 2 and amended claim 1.

The amendment to the claims received on April 25, 2007 canceled claims 23-24 and amended claim 1.

The amendment to the claims received on November 19, 2007 amended claims 1 and 16.

The amendment to the claims received on May 7, 2008 amended claim 1, canceled claim 5, and added new claim 25.

Claims 1, 3-4, 6-22, and 25 are currently pending.

Claims 1, 3-4, 6-15, 19-22, and 25 are currently under consideration.

Election/Restrictions

3. Applicants elected, without traverse, Group I in the reply filed on February 10, 2006. Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

4. The species requirement is withdrawn upon further consideration. Previously withdrawn claims 8, 13, 15, and 19-22 are rejoined.

Priority

5. The present application claims status as a DIV of 08/776,188 filed January 24, 1997 (now U.S. Patent 6,613,530) which is a national stage (i.e. 371) of PCT/EP95/02919 filed July 24, 1995. In addition, the present applications claims foreign priority to German applications P 44 26 276.0 filed July 25, 1994 and P 44 30 972.4 filed August 31, 1994.

Invention as Claimed

6. A method for detection of an antibody against a pathogenic organism in a liquid sample wherein said pathogenic organism is selected from the group consisting of bacteria, viruses, and protozoa, the method comprising: (a) incubating the following: (1) sample, (2) a solid phase, (3) a first antigen for said antibody wherein the first antigen comprises at least one marker group and comprises multiple epitope regions, said epitope regions being identical in amino acid sequence, and (4) a second antigen for said antibody wherein the second antigen binds to the solid phase under conditions to obtain a complex comprising a solid phase-bound second antigen to which is bound the antibody and to which is bound the first antigen and (b) detecting said antibody by direct or indirect detection of the complex on said solid phase said first antigen is of formula $(P-)_nT(-L)_n$ (i.e. Ia) or $T(-P-L_m)_n$ (i.e. Ib) wherein T is a carrier, P is a peptide comprising an epitope region wherein said epitope region is reactive with the antibody, L is the marker group in said first antigen, - is a covalent coupling, n is 2-40, and m is 1-10 and variations thereof.

Withdrawn Objection

7. The objection to claims 1, 3-4, 6-7, 9-12, and 14 is withdrawn in view of the claim amendments received on May 7, 2008.

New Objections

Claim Objections

8. Claim 1 is objected to because of the following informalities: viruses should be virus and protozoa should be protozoan (i.e. singular corresponds to singular organism). Appropriate correction is required.

9. Claim 1 is objected to because of the following informalities: "first antigen…comprises at least one marker group and comprises multiple epitope regions said epitope regions being identical in amino acid seqeunce" is considered redundant in view of formulas (Ia) and (Ib). Appropriate correction is required.

10. Claim 4 is objected to because of the following informalities: claim 4 is redundant in view of the formulas of claim 1 and claim 3. Appropriate correction is required.

11. Claim 9 is objected to because of the following informalities: the claim should read "wherein the at least one of the first antigen or the second antigen". Appropriate correction is required. In addition, the limitation of "comprises a carrier to which the epitope regions are covalently coupled" is redundant due to the formulas in claim 1.

12. Claim 13 is objected to because of the following informalities: the limitation "multimeric antigen comprising multiple, identical epitope regions…said epitope regions being identical in amino acid sequence" is redundant due to the formulas in claim 1. Appropriate correction is required.

Withdrawn Rejections

13. The rejection of claims 1, 3-4, 6, 9, 12, and 14 under 35 U.S.C. 102(e) as being anticipated by Flavell et al. U.S. Patent 5,618,533 filed December 10, 1993 is withdrawn in view of the necessity of more than one marker (see formulas). However, "at least one marker" is present in section (3) of claim 1 (see 35 USC 112, second paragraph rejection below).

14. The rejection of claims 1, 3-4, 6-7, 9-12, and 14 under 35 U.S.C. 103(a) as being unpatentable over Rejman et al. EP 0 507 586 (supplied by applicants in IDS), Formoso et al. WO 90/07119 published June 28, 1990, and Watts et al. U.S. Patent 5,437,983 filed February 1, 1993 is withdrawn in view of the necessity of more than one marker (see formulas). However, "at least one marker" is present in section (3) of claim 1 (see 35 USC 112, second paragraph rejection below).

New Rejections

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1, 3-4, 6-15, 19-22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention.

A. Independent claim 1 requires "a first antigen for said antibody, wherein the first antigen comprises at least one marker group" in section (3) and then requires "the first antigen is of formula (Ia) or (Ib)" wherein 2-400 marker groups are required. Therefore, what is the minimum number of marker groups required (1, 2, etc.)?

B. A nexus is missing between the preamble and the last method step (i.e. detection of an antibody against a pathogenic organism selected from the group consisting of a bacteria, virus, and protozoa).

C. Claim 1 recites the limitation "said sample" in section (1). There is insufficient antecedent basis for this limitation in the claim. "[S]aid liquid sample" is suggested.

D. Claim 6 requires "the first antigen having the marker group comprising a hapten and a binding partner of the hapten being labeled with a signal generating group". Claim 1 requires "the first antigen is of formula (Ia) or (Ib)" which are $(P\text{-})_nT(\text{-}L)_n$ and $T(\text{-}P\text{-}L_m)_n$, respectively. Therefore, it is not clear if the hapten of claim 6 is P (peptide) or part of L (marker), if the hapten-binding partner of the hapten-signal generating group is L, etc. In addition, if the hapten is P, then claim 7 should correlate to bacteria, virus, or protozoan haptens.

E. Claim 13 requires P to have an inactive spacer region. However, it is not clear if every epitope has a spacer region (i.e. P = epitope-spacer region which are repeated n number of times) or if the spacer region is an additional structure not found in formula (Ia) or (Ib).

F. Claim 14 requires P to comprise "a single epitope region or a multiple of an epitope region". This is not clear due to formulas (Ia) and (Ib). For example, if P is a multiple epitope region then is n still 2-40?

G. Claim 15 optionally has P epitopes linked by spacer regions. However, it is not clear if every epitope has a spacer region (i.e. P = epitope-spacer region which are repeated n number of times) or if the spacer region is an additional structure not found in formula (Ia) or (Ib). In addition, claim 15 states that P is a mosaic peptide comprising multiple, immunologically reactive epitope regions. However, it is not clear if P has multiple epitope regions or if P_n has multiple epitope regions (see the formulas in claim 1). Furthermore, claim 15 requires the first antigen and the second antigen to be a recombinant fusion polypeptide. However, it is not clear how this if reflected in formulas (Ia) or (Ib).

H. Claim 21 recites the limitation "the several copies of the single epitope" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

I. Claim 21 requires spacer regions. However, it is not clear if every epitope has a spacer region (i.e. P = epitope-spacer region which are repeated n number of times) or if the spacer region is an additional structure not found in formula (Ia) or (Ib).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Amber D. Steele/
Patent Examiner, Art Unit 1639

February 3, 2009